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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,836	03/15/2002	Jean-Louis Dasseux	9196-0022-999	5585

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EXAMINER	
CELSA, BENNETT M	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,836	DASSEUX ET AL.	
	Examiner	Art Unit	
	Bennett Celsa	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-18, 20-27, 29, 34, 35, 37, 42, 44 and 54-56* is/are pending in the application.

4a) Of the above claim(s) *10,11,17,20-27,44 and 54-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9,12-16,18,29,34,35,37 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/15/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1, 3-18, 20-27, 29, 34, 35, 37, 42, 44 and 54-56 are currently pending.

Claims 1 (in part), 3-9, 12-16(in part), 18 (in part), 29 (in part), 34 (in part), 35 (in part), 37 (in part) and 42 (in part) are under consideration.

Claims 10-11, 17, 20-27, 44 and 54-56 are withdrawn from consideration as being directed to a non-elected invention.

Election/Restrictions

Applicant's election of Group I (claims 1 in part, 3-9, 12-18 in part, 29 in part, 34, in part, 35 in part, 37 in part and 42 in part) in the reply filed on 8/19/04 and applicant's further election of the species of SEQ ID 4 (PVLDLFRELLNELLEALKQKLK), which reads on claims 1 in part, 3-9, 12-16 in part, 18 in part, 29 in part, 34 in part, 35 in part, 37 in part and 42 in part is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 10-11, 17, 20-27, 44 and 54-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Right of Rejoinder

It is noted that the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in

accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

I. Claims 1, 3-6, 9, 12-13, 16, 18 and 37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-49 of U.S. Patent No. 6,046,166 in view of Garber et al., Arteriosclerosis & Thrombosis, Vol. 12(8) (1992) pages 886-94.

The Patent claims disclose compounds and pharmaceutical compositions thereof which are within the scope of the presently claimed 22-29 residue "altered "ApoA-I agonist peptide compounds Z1-X1-X23-Z2 containing conservative amino acids (e.g. conservative substitution of Asn/Gln for acid/base at X8). The patented compounds differ from the presently claimed invention by failing to teach the substitution of D-amino acids for L-amino acids.

However, the Garber et al. reference provides motivation to one of ordinary skill in the art to substitute D-amino acids for L-amino acids in order to produce Apo-A-I agonist analogs which are "less susceptible to in vivo proteolytic degradation" while retaining comparable biological activity (e.g. residence time; clearance; lipid affinity) to its corresponding L-amino acid containing peptide. See entire Garber article, but particularly, abstract; page 887, left column; Tables 2-4; Figures 1-4; and "Discussion" on pages 891 (right column) to page 893, particularly page 892, right column 2nd full paragraph.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the patented compounds (and

compositions thereof) to incorporate one or more D-Amino acids in order to obtain Apo-A-1 agonist analogues which are less susceptible to in vivo proteolytic degradation while retaining comparable biological acitivity to the corresponding L-amino acid containing peptides.

II. Claims 1, 3-9, 12-16, 18 and 37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,329,341 in view of Garber et al., Arteriosclerosis & Thrombosis, Vol. 12(8) (1992) pages 886-94.

The Patent claims disclose methods which describe the use of compounds and pharmaceutical compositions thereof which are within the scope of the presently claimed 22-29 residue unaltered and "altered " ApoA-I agonist peptide compounds Z1-X1-X23-Z2 containing conservative amino acids. The compounds/compositions taught by the patented claims differ from the presently claimed invention by failing to teach the substitution of D-amino acids for L-amino acids.

However, the Garber et al. reference provides motivation to one of ordinary skill in the art to substitute D-amino acids for L-amino acids in order to produce Apo-A-I agonist analogs which are "less susceptible to in vivo proteolytic degradation" while retaining comparable biological activity (e.g. residence time; clearance; lipid affinity) to its corresponding L-amino acid containing peptide. See entire Garber article, but particularly, abstract; page 887, left column; Tables 2-4; Figures 1-4; and "Discussion" on pages 891 (right column) to page 893, particularly page 892, right column 2nd full paragraph.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the patented compounds (and compositions thereof) to incorporate one or more D-Amino acids in order to obtain Apo-A-1 agonist analogues which are less susceptible to in vivo proteolytic degradation while retaining comparable biological acitivity to the corresponding L-amino acid containing peptides.

III. Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,376,464 in view of Garber et al., Arteriosclerosis & Thrombosis, Vol. 12(8) (1992) pages 886-94.

The Patent claims disclose lipid complexes of ApoA-I agonist peptide compounds Z1-X1-X23-Z2 and compositions compising unaltered and altered (e.g. substitution of one or more conservative amino acids). The lipid complexes and/or compounds/compositions taught by the patented claims differ from the presently claimed invention by failing to teach the substitution of D-amino acids for L-amino acids.

However, the Garber et al. reference provides motivation to one of ordinary skill in the art to substitute D-amino acids for L-amino acids in order to produce Apo-A-I agonist analogs which are "less susceptible to in vivo proteolytic degradation" while retaining comparable biological activity (e.g. residence time; clearance; lipid affinity) to its corresponding L-amino acid containing peptide. See entire Garber article, but particularly, abstract; page 887, left column; Tables 2-4; Figures 1-4; and "Discussion"

on pages 891 (right column) to page 893, particularly page 892, right column 2nd full paragraph.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the patented compounds (and compositions thereof) to incorporate one or more D-Amino acids in order to obtain Apo-A-1 agonist analogues which are less susceptible to in vivo proteolytic degradation while retaining comparable biological acitivity to the corresponding L-amino acid containing peptides.

IV. Claims 1, 3-9, 12-16, 18 and 37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,518,412 in view of Garber et al., Arteriosclerosis & Thrombosis, Vol. 12(8) (1992) pages 886-94.

The Patent claims ApoA-I agonist peptide compounds Z1-X1-X23-Z2 and compositions comprising unaltered and altered (e.g. substitution of one or more conservative amino acids at any of X1-X23) and their encoding nucleic acids. The ApoA-1 compounds/compositions taught by the patented claims differ from the presently claimed invention by failing to teach the substitution of D-amino acids for L-amino acids.

However, the Garber et al. reference provides motivation to one of ordinary skill in the art to substitute D-amino acids for L-amino acids in order to produce Apo-A-I agonist analogs which are "less susceptible to in vivo proteolytic degradation" while

retaining comparable biological activity (e.g. residence time; clearance; lipid affinity) to its corresponding L-amino acid containing peptide. See entire Garber article, but particularly, abstract; page 887, left column; Tables 2-4; Figures 1-4; and "Discussion" on pages 891 (right column) to page 893, particularly page 892, right column 2nd full paragraph.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the patented compounds (and compositions thereof) to incorporate one or more D-Amino acids in order to obtain Apo-A-1 agonist analogues which are less susceptible to in vivo proteolytic degradation while retaining comparable biological acitivity to the corresponding L-amino acid containing peptides.

V. Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,573,239 in view of Garber et al., Arteriosclerosis & Thrombosis, Vol. 12(8) (1992) pages 886-94.

The Patent claims disclose lipid complexes of ApoA-I agonist peptide compounds Z1-X1-X23-Z2 and compositions comprising unaltered and altered (e.g. substitution of one or more conservative amino acids). The lipid complexes and/or compounds/compositions taught by the patented claims differ from the presently claimed invention by failing to teach the substitution of D-amino acids for L-amino acids.

However, the Garber et al. reference provides motivation to one of ordinary skill in the art to substitute D-amino acids for L-amino acids in order to produce Apo-A-I agonist analogs which are "less susceptible to in vivo proteolytic degradation" while retaining comparable biological activity (e.g. residence time; clearance; lipid affinity) to its corresponding L-amino acid containing peptide. See entire Garber article, but particularly, abstract; page 887, left column; Tables 2-4; Figures 1-4; and "Discussion" on pages 891 (right column) to page 893, particularly page 892, right column 2nd full paragraph.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the patented compounds (and compositions thereof) to incorporate one or more D-Amino acids in order to obtain Apo-A-1 agonist analogues which are less susceptible to in vivo proteolytic degradation while retaining comparable biological acitivity to the corresponding L-amino acid containing peptides.

VI. Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,630,450 in view of Garber et al., Arteriosclerosis & Thrombosis, Vol. 12(8) (1992) pages 886-94.

The Patent claims disclose methods which describe the use of compounds (and lipid complexes) and pharmaceutical compositions thereof which are within the scope of the presently claimed 22-29 residue unaltered and "altered " ApoA-I agonist peptide

compounds Z1-X1-X23-Z2 containing conservative amino acids. The compounds/compositions taught by the patented claims differ from the presently claimed invention by failing to teach the substitution of D-amino acids for L-amino acids.

However, the Garber et al. reference provides motivation to one of ordinary skill in the art to substitute D-amino acids for L-amino acids in order to produce Apo-A-I agonist analogs which are "less susceptible to in vivo proteolytic degradation" while retaining comparable biological activity (e.g. residence time; clearance; lipid affinity) to its corresponding L-amino acid containing peptide. See entire Garber article, but particularly, abstract; page 887, left column; Tables 2-4; Figures 1-4; and "Discussion" on pages 891 (right column) to page 893, particularly page 892, right column 2nd full paragraph.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the patented compounds (and compositions thereof) to incorporate one or more D-Amino acids in order to obtain Apo-A-1 agonist analogues which are less susceptible to in vivo proteolytic degradation while retaining comparable biological acitivity to the corresponding L-amino acid containing peptides.

Provisional Double Patenting

VII. Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 (particularly claims 1-19 and 29-43) of copending

application 10/802,080 in view of Garber et al., Arteriosclerosis & Thrombosis, Vol. 12(8) (1992) pages 886-94. This is a provisional obviousness-type double patenting rejection.

The Patent application claims disclose compounds (and lipid complexes) and pharmaceutical compositions thereof which are within the scope of the presently claimed 22-29 residue unaltered and "altered " ApoA-I agonist peptide compounds Z1-X1-X23-Z2 containing conservative amino acids. The compounds/compositions taught by the patent application claims differ from the presently claimed invention by failing to teach the substitution of D-amino acids for L-amino acids.

However, the Garber et al. reference provides motivation to one of ordinary skill in the art to substitute D-amino acids for L-amino acids in order to produce Apo-A-I agonist analogs which are "less susceptible to in vivo proteolytic degradation" while retaining comparable biological activity (e.g. residence time; clearance; lipid affinity) to its corresponding L-amino acid containing peptide. See entire Garber article, but particularly, abstract; page 887, left column; Tables 2-4; Figures 1-4; and "Discussion" on pages 891 (right column) to page 893, particularly page 892, right column 2nd full paragraph.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the patented application claimed compounds (and compositions thereof) to incorporate one or more D-Amino acids in order to obtain Apo-A-1 agonist analogues which are less susceptible to in vivo

proteolytic degradation while retaining comparable biological acitivity to the corresponding L-amino acid containing peptides.

VIII. Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-68 of copending application 10/283,599 in view of Garber et al., Arteriosclerosis & Thrombosis, Vol. 12(8) (1992) pages 886-94. This is a provisional obviousness-type double patenting rejection.

The Patent application claims disclose compounds (and lipid complexes) and pharmaceutical compositions (and encoding nucleic acids) which are within the scope of the presently claimed 22-29 residue unaltered and "altered " ApoA-I agonist peptide compounds Z1-X1-X23-Z2 containing conservative amino acids. The compounds/compositions taught by the patent application claims differ from the presently claimed invention by failing to teach the substitution of D-amino acids for L-amino acids.

However, the Garber et al. reference provides motivation to one of ordinary skill in the art to substitute D-amino acids for L-amino acids in order to produce Apo-A-I agonist analogs which are "less susceptible to in vivo proteolytic degradation" while retaining comparable biological activity (e.g. residence time; clearance; lipid affinity) to its corresponding L-amino acid containing peptide. See entire Garber article, but particularly, abstract; page 887, left column; Tables 2-4; Figures 1-4; and "Discussion"

on pages 891 (right column) to page 893, particularly page 892, right column 2nd full paragraph.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the patented application claimed compounds (and compositions thereof) to incorporate one or more D-Amino acids in order to obtain Apo-A-1 agonist analogues which are less susceptible to in vivo proteolytic degradation while retaining comparable biological acitivity to the corresponding L-amino acid containing peptides.

IX. Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-55 (particularly claims 1-18 and 28-42) of copending application 10/099,574 in view of Garber et al., Arteriosclerosis & Thrombosis, Vol. 12(8) (1992) pages 886-94. This is a provisional obviousness-type double patenting rejection.

The Patent application claims disclose compounds (and lipid complexes) and pharmaceutical compositions which are within the scope of the presently claimed 22-29 residue unaltered and "altered " ApoA-I agonist peptide compounds Z1-X1-X23-Z2 containing conservative amino acids. The compounds/compositions taught by the patent application claims differ from the presently claimed invention by failing to teach the substitution of D-amino acids for L-amino acids.

However, the Garber et al. reference provides motivation to one of ordinary skill in the art to substitute D-amino acids for L-amino acids in order to produce Apo-A-I agonist analogs which are "less susceptible to in vivo proteolytic degradation" while retaining comparable biological activity (e.g. residence time; clearance; lipid affinity) to its corresponding L-amino acid containing peptide. See entire Garber article, but particularly, abstract; page 887, left column; Tables 2-4; Figures 1-4; and "Discussion" on pages 891 (right column) to page 893, particularly page 892, right column 2nd full paragraph.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the patented application claimed compounds (and compositions thereof) to incorporate one or more D-Amino acids in order to obtain Apo-A-1 agonist analogues which are less susceptible to in vivo proteolytic degradation while retaining comparable biological activity to the corresponding L-amino acid containing peptides.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639

BC
October 19, 2004